

REMARKS

Entry of the foregoing, reexamination, and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

I. Amendments to the Claims

By the foregoing amendment, claims 25, 28-32, 34-36, 43, and 46 have been amended, claims 26, 27, 33, 44, and 45 have been canceled, and new claims 47-52 have been added.

In particular, claim 25 has been amended to clarify that the inventive selection system comprises a bacterial cell deficient of L-ribulose-5-phosphate 4-epimerase into which a vector carrying a nucleic acid sequence encoding an active L-ribulose-5-phosphate 4-epimerase has been added as a selection marker. Support for this amendment can be found throughout the application as filed, for example at page 7, lines 23-27 of the specification (stating that the *araD* gene product is L-ribulose-5-phosphate 4-epimerase). *See also* page 9, lines 10-12 ("in the present connection the term "deficient" denotes a host in which the *araD* gene is either totally deleted or inactivated by any known method"). A corresponding amendment has been made to claim 43.

Claims 25, 32, 34, and 43 have been amended by deleting the phrase "or a catalytically active fragment thereof."

Claims 28 and 46 have been amendment to depend from claims 47 and 48, respectively.

Other amendments to the claims have been made to clarify the claim language and bring the claims into better conformance with U.S. patent practice. These amendments are

merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

New claims 47-52 recite particular embodiments of the inventions recited in claims 25 and 43.

The amendments to the claims, including cancellation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application are respectfully requested.

II. Sequence Compliance

At page 2 of the Office Action, the Examiner has stated that the present application fails to comply with the Sequence Listing requirements under 37 C.F.R. §§ 1.821(a)(1) and (a)(2).

Specifically, the Examiner has indicated that Figures 13, 22, and 23 of the application include nucleotide and/or amino acid sequences that are not associated with sequence identifiers.

In response, Applicants submit herewith a substitute Sequence Listing that contains all of the sequences, disclosed in the specification and drawings, that are encompassed by the sequence definitions set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). In particular, Applicants submit herewith a computer readable form (CRF) copy of the substitute Sequence Listing, a paper copy of the substitute Sequence Listing, and the required statement to support the substitute Sequence Listing.

In addition, Applicants have amended the description of the drawings section of the specification to identify each sequence disclosed in Figures 13, 22, and 23 with the corresponding sequence identification number.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this objection.

III. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

At pages 3-5 of the Office Action, claims 25-36 and 43-46 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

In particular, the Examiner has stated that the specification does not sufficiently describe the catalytic *araD* fragments, mutated *araD* genes, nuclear binding proteins, or multimerized DNA binding sites that are encompassed by the claims.

As noted above, the claims have been amended to clarify that the inventive selection system comprises a bacterial cell deficient of L-ribulose-5-phosphate 4-epimerase into which a vector carrying a nucleic acid sequence encoding an active L-ribulose-5-phosphate 4-epimerase has been added as a selection marker. This amendment highlights a characteristic feature of the invention, namely the ability of the system to link successful insertion of the vector to restoration of L-ribulose-5-phosphate 4-epimerase enzyme expression and activity in an L-ribulose-5-phosphate 4-epimerase-deficient host cell. As also noted above, the claims no longer recite "catalytically active fragments."

Applicants note that the specification supports *araD* genes (*i.e.* nucleic acid sequences encoding L-ribulose-5-phosphate 4-epimerase) from organisms other than *E. coli*. For

example, the specification states that "the *araD* gene [is] involved in the pentose pathway of both prokaryotic and eukaryotic organisms" (page 6, lines 19-21).

Furthermore, information which is known in the art need not be described in detail in the specification (*see, e.g. Hybritech, Inc v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986)). In addition, satisfaction of the written description requirement does not require either recitation or incorporation by reference of publicly accessible sequences (*see, e.g. Falkner v. Ingles*, 79 USPQ2d 1001 (Fed. Cir. 2006) and *Capon v. Eshhar*, 76 USPQ 1078 (Fed. Cir. 2005)).

With regard to the present application, Applicants submit that nucleic acid sequences encoding L-ribulose-5-phosphate 4-epimerase were well known and had been extensively studied as of the filing date of the present application. In particular, numerous literature references describing L-ribulose-5-phosphate 4-epimerase coding sequences were available at the time of filing. Deupree et al., *J. Biol. Chem.* 247:3093-3097 (1970) (a copy of which is submitted herewith), for example, refers to the fact that L-ribulose-5-phosphate 4-epimerase is an enzyme which is well known to be present in several microorganisms, such as *E. coli*, *Lactobacillus plantarum*, *Bacillus subtilis*, and *Aerobacter aerogenes*. *See also* Sá-Nogueira et al., *Microbiol.* 143:957-969 (1997) (submitted herewith), which describes the *ara* operon in *Bacillus Subtilis*. Sequences from *Shigella flexneri*, *Salmonella typhimurium*, *Salmonella enterica*, *Yersinia pestis*, *Pasteurella multocida*, *Haemophilus influenzae*, *Oceanobacillus iheyensis*, and *Bacillus halodurans* were also known in the art, and have been submitted herewith for the Examiner's reference. Thus, the present specification, along with the prior art at the time of filing, provided sufficient information to envisage the nucleic acid sequences that would be suitable for the present invention.

Hence, Applicants submit that the written description requirement is met for the entire scope of the claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Response to Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

At page 5-6 of the Office Action, claims 25-36 and 43-46 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for the following reasons.

A. The Examiner has stated that the claims are indefinite for reciting "an *araD* gene, or a catalytically active fragment thereof," since genes are not generally catalytically active.

The phrase "catalytically active fragments" has been deleted from the claims, rendering this aspect of the indefiniteness rejection moot.

B. The Examiner has also stated that dependent claim 27 is indefinite for recitation of "said *araD* gene," since it is not clear which of the two *araD* genes recited in claim 25 is intended.

Claim 27 has been canceled, rendering this aspect of the indefiniteness rejection moot as well.

C. Finally, the Examiner has stated that claim 36 is indefinite for recitation of "Shine-Delgarno sequence," since the term lacks antecedent basis.

Claim 36 has been amended to recite "the Shine-Delgarno sequence of the *araD* gene."

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

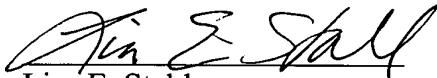
From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 838-6609 so that prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: 
Lisa E. Stahl
Registration No. 56,704

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620